requirements of this section and section 502(f)(1) of the act if it meets the requirements of § 809.10 of this chapter.

[41 FR 6910, Feb. 13, 1976]

§ 201.120 Prescription chemicals and other prescription components.

A drug prepared, packaged, and primarily sold as a prescription chemical or other component for use by registered pharmacists in compounding prescriptions or for dispensing in dosage unit form upon prescriptions shall be exempt from section 502(f)(1) of the act if all the following conditions are met:

(a) The drug is an official liquid acid or official liquid alkali, or is not a liquid solution, emulsion, suspension, tablet, capsule, or other dosage unit form; and

(b) The label of the drug bears:

(1) The statement ''For prescription compounding''; and

(2) If in substantially all dosage forms in which it may be dispensed it is subject to section 503(b)(1) of the act, the statement ''Caution: Federal law prohibits dispensing without prescription''; or

(3) If it is not subject to section 503(b)(1) of the act and is by custom among retail pharmacists sold in or from the interstate package for use by consumers, ''adequate directions for use'' in the conditions for which it is so sold.

Provided, however, That the information referred to in paragraph (b)(3) of this section may be contained in the labeling on or within the package from which it is to be dispensed.

(c) This exemption shall not apply to any substance intended for use in compounding which results in a new drug, unless an approved new-drug application covers such use of the drug in compounding prescriptions.

EFFECTIVE DATE NOTE: At 67 FR 4906, Feb. 1, 2002, § 201.120 was amended in paragraph (b)(2) by removing the phrase '' 'Caution: Federal law prohibits dispensing without prescription' '' and by adding in its place the phrase '' 'Rx only' '', effective April 2, 2002.

§ 201.122 Drugs for processing, repacking, or manufacturing.

A drug in a bulk package, except tablets, capsules, or other dosage unit forms, intended for processing, repacking, or use in the manufacture of another drug shall be exempt from section 502(f)(1) of the act if its label bears the statement ''Caution: For manufacturing, processing, or repacking''; and if in substantially all dosage forms in which it may be dispensed it is subject to section 503(b)(1) of the act, the statement ''Caution: Federal law prohibits dispensing without prescription'', or if in substantially all dosage forms in which it may be dispensed it is subject to section 503(f)(1) of the act, the statement ''Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian''. This exemption and the exemption under § 201.120 may be claimed for the same article. However, the exemption shall not apply to a substance intended for a use in manufacture, processing, or repacking which causes the finished article to be a new drug or new animal drug, unless:

(a) An approved new drug application or new animal drug application covers the production and delivery of the drug substance to the application holder by persons named in the application, and, for a new drug substance, the export of it by such persons under § 314.410 of this chapter; or

(b) If no application is approved with respect to such new drug or new animal drug, the label statement ''Caution: For manufacturing, processing, or repacking'' is immediately supplemented by the words ''in the preparation of a new drug or new animal drug limited by Federal law to investigational use'', and the delivery is made for use only in the manufacture of such new drug or new animal drug limited to investigational use as provided in part 312 or § 511.1 of this chapter; or

(c) A new drug application or new animal drug application covering the use of the drug substance in the production and marketing of a finished drug product has been submitted but not yet approved or disapproved, the